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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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CROWELL AND MORNING
INTELLECTUAL PROPERTY GROUP
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EXAMINER

BRANNOCK, MICHAEL T

| ART UNIT | PAPER NUMBER |
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1646

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/825,882

Applicant(s)

ADLER, JON ELLIOT

Examiner

Michael Brannock

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 5/14/03 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 May 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): see attachment.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 158-185.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

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Attachment to Advisory Action

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth 5/14/04, have been entered in full.

Response to Amendment

Applicant is notified that any remaining rejection or objection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Priority

The prior denial of Applicant's claim for domestic priority under 35 U.S.C. 119(e) is withdrawn in view of Applicant's persuasive arguments.

Maintained Rejections

New claims 158-185 are rejected under 35 U.S.C. § 101, as applied previously to claims 138-157, because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, for the reasons of record.

Applicant's arguments and the Zoller Declaration (5/14/04) regarding the post filing date evidence establishing SEQ ID NO: 8 as a functional bitter taste receptor have been fully considered but not deemed persuasive. The specification says nothing about SEQ ID NO: 8 binding to nitrosaccharin, and the examiner can think of no way to use SEQ ID NO: 8 in a way that constitutes a substantial utility without this knowledge. At the top of page 9 of Applicant's response, Applicant effectively makes the examiner's point. Applicant argues that "In fact, Dr.

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Zoller noted that based on hT2R61's specific activation by nitrososaccharin, this receptor can be used in cell based assays to identify compounds that modulate, preferably block the bitter taste of saccharin." This is absolutely correct. The examiner can think of no assay that could be used to block the specific activation of hT2R61 without using nitrososaccharin. Conversely, the invitation to perform extensive investigation to try to find a ligand that activates hT2R61, does not constitute a substantial utility.

Applicant's arguments, on page 12, regarding the probative value of Lindemann are persuasive in part, it is agreed that Chandrashekar and Adler provide the evidence that certain T2R members are, in fact, bitter tastant receptors. However, the state of the art, exemplified by Chandrashekar and Adler, indicates that it was impossible to predict that a particular T2R would bind a bitter tastant. Chandrashekar tested 25 murine T2Rs and found only two that responded to a bitter ligand (mT2R-5 and mTR2-8). They also tested 11 human T2Rs and found only one that responded to a bitter ligand.

Applicant's arguments regarding the functional data provided by Chandrashekar and Adler have been fully considered. It is not convincing that one of skill in the art would view the fact that 3 of 36 T2Rs examined actually bind bitter tastants as providing a reasonable expectation that any other T2R would bind a bitter ligand.

Applicant argues that Chandrashekar provide further evidence that the skilled artisan would know to assay saccharin as one of the potential bitter tastants. Applicant asserts that another group, Buke et al, recently presented an abstract that indicates that saccharin activates hT2R61, presumably at high concentrations although the examiner was unable to obtain a copy of this reference. Applicant then asserts that because saccharin was one of the compounds used

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by Chandrashekar, then this is evidence that would lead to the use saccharin as one of the potential bitter tastants. This argument has been fully considered but not deemed persuasive. It is not at all clear that Chandrashekar used saccharin as a potential bitter tastant, rather it appears that Chandrashekar use it as a sweet tastant, i.e. the concentration was 10 mM and is not indicated to be high so as to be perceived as bitter. Further, none of the T2R receptors taught by Chandrashekar actually bound saccharin.

The Zoller Declaration also indicates that another post-filing date paper by Buke et al demonstrates that another T2R binds the bitter tastant salicin. This argument has been fully considered but not deemed persuasive. This paper appears to be another example of the unpredictability and lack of reasonable success when trying to match a particular T2R to its ligand. Buke et al. tested 24 T2Rs and found a ligand for only one of them. Strikingly, they were unable to find a ligand to the instant hT2R61 which they term TASR44.

Applicant's additional arguments regarding Perruccio and Kleinhaus are not persuasive. The examiner maintains that the work of Chandrashekar and of Adler, regarding three receptors and three ligands, do not solve the complexities of bitter taste perception as detailed by Perruccio and Kleinhaus.

Claims 158-185 also rejected under 35 U.S.C. § 112 first paragraph, as set forth previously regarding claims 138-157. Specifically, since the claimed invention is not supported by a substantial asserted utility, for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

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Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above.

Additionally, as set forth previously, should Applicant establish a substantial utility for the claimed polynucleotides, claims 158, 159, 164-185 encompass polynucleotides encoding polypeptide variants of the polypeptide of SEQ ID NO: 8 i.e. substitutions, deletions or insertions in a protein corresponding to SEQ ID NO: 8 or comprising only portions of SEQ ID NO: 8. Applicant has not provided sufficient guidance as to how to make and use the encoded polypeptides which are not 100% identical to the polypeptide of SEQ ID NO: 8, but which still retain a desired property of the polypeptide of SEQ ID NO: 8, as set forth previously. Applicant's arguments have been substantially addressed previously.

Claims 158, 159, 164-185 are rejected under 35 U.S.C. 112, first paragraph, as set forth previously regarding claims 138, 141-157, i.e. as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's arguments have been substantially addressed previously.

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Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

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June 5, 2004